IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

RAMONA SHELLEY, **Plaintiff,** **v.** **ETHICON, INC.; and JOHNSON & JOHNSON,** **Defendants.**	**CIVIL ACTION** **NO. 12-6862**

DuBois, J. **July 9, 2013**

M E M O R A N D U M

I. INTRODUCTION

Plaintiff Ramona Shelley brings this suit for injuries allegedly caused by an implanted surgical mesh, Prolene TM soft mesh, manufactured and distributed by defendants Ethicon, Inc. and Johnson & Johnson for use in repairing ventral hernias. The Complaint sets forth seven separate claims against both defendants: (1) negligence, (2) strict liability–product defect, (3) strict liability–failure to warn, (4) breach of express warranty, (5) breach of implied warranty, (6) negligent misrepresentation, and (7) fraudulent misrepresentation. Defendants move to dismiss certain of Shelley's claims.

II. LEGAL STANDARD

Rule 12(b) (6) of the Federal Rules of Civil Procedure provides that, in response to a pleading, a defense of "failure to state a claim upon which relief can be granted" may be raised by motion. In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the Court "accept[s] all factual allegations as true, [and] construe[s] the complaint in the light most favorable to the plaintiff . . . ." Phillips v. County of Allegheny, 515 F.3d 224, 231, 233 (3d Cir. 2008) (internal quotations omitted).

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level . . . .'" Victaulic Co. v. Tieman, 499 F.3d 227, 234 (3d Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). A complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). To satisfy the plausibility standard, a plaintiff's allegations must show that defendant's liability is more than "a sheer possibility." Id. "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" Id. (quoting Twombly, 550 U.S. at 557).

III. DISCUSSION

Defendants move to dismiss certain of Shelley's claims for two reasons. First, defendants argue that as Johnson & Johnson is merely a holding company, all claims asserted against Johnson & Johnson should be dismissed. Second, defendants claim that Shelley's non-negligence causes of action fail to state a claim upon which relief can be granted under Pennsylvania law and should be dismissed. The Court addresses these arguments in turn.

1. Claims Against Johnson & Johnson

First, defendants aver that Johnson & Johnson is "a holding company that does not design, develop, manufacture, market, promote or sell any product." (Mot. at 5.) Specifically, defendants argue that Johnson & Johnson did not manufacture Prolene TM soft mesh and that it therefore owed no duty of care to Shelley and that all claims asserted against Johnson & Johnson should be dismissed. In support of this contention, defendants cite the Declaration of Douglas K. Chia, Secretary of Johnson & Johnson. Defendants concede that "[c]onsideration of this

declaration requires conversion of certain portions of Defendants' motion to one for summary judgment," pursuant to Fed. R. Civ. P. 12(d). (Mot. at 3.)

The Court rejects defendants' argument with respect to Johnson & Johnson. The parties have not conducted any discovery, and as such, treatment of the instant Motion as one for summary judgment would be inappropriate at this stage in the litigation. Accordingly, the Court does not consider the Declaration submitted by defendants. Further, "at this early stage, factual determinations [as to corporate status] are not appropriate." Apple Computer, Inc. v. Unova, Inc., 2003 WL 22928034, *6 (D. Del. Nov. 25, 2003).

Plaintiff has alleged that both defendants "designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and/or sold by defendants . . . . " (Compl. at ¶16.) Plaintiff thus states a plausible claim for liability on the part of Johnson & Johnson. Defendants' motion on this ground is denied.

2. Non-Negligence Claims

Defendants next argue that plaintiff's non-negligence claims, those in Counts II through V, and VII, are improper as a matter of Pennsylvania law. As a threshold matter, the Court's analysis is based on Hahn v. Richter, 543 Pa. 558, 563 (Pa. 1996), which in turn is based on the Restatement (Second) of Torts. However, the Pennsylvania Supreme Court has recently granted allocatur on the question of whether Pennsylvania will adopt the strict liability analysis of the Restatement (Third) of Torts. See Tincher v. Omega Flex, Inc., 64 A.3d 626 (Pa. 2013). In the event the Pennsylvania Supreme Court adopts the strict liability analysis of the Restatement (Third) of Torts, this Court will entertain motions for reconsideration if either party concludes that the result would be different under the Restatement (Third) of Torts.

The Court first addresses Counts II and III of the Complaint. It will then address Counts IV, V and VII in turn.

Plaintiff asserts two strict liability claims: Count II of the Complaint alleges strict liability based on a design defect, and Count III alleges strict liability based on failure to warn. However, applying comment k of § 402A of the Restatement (Second) of Torts, the Pennsylvania Supreme Court has ruled that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." Hahn v. Richter, 543 Pa. 558, 563 (Pa. 1996).

Hahn has been broadly applied to both prescription drugs as well as prescription medical devices. See Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) ("We find no reason why the same rational applicable to prescription drugs may not be applied to medical devices."). Thus, "Pennsylvania law does not recognize a strict-liability claim based on a design defect or a failure to warn as a viable cause of action against a manufacturer of prescription drugs or devices . . . . " Doughtery v. C.R. Bard, Inc., 2012 WL 2940727, at *6 (E.D. Pa. July 18, 2012); see also Tatum v. Takeda Pharmaceuticals N. Am., Inc., 2012 WL 5182895, at *2 (E.D. Pa. Oct. 19, 2012) (DuBois, J.). Accordingly, that part of defendants' Motion which seeks dismissal of Counts II and III is granted, and Counts II and III are dismissed with prejudice.

Count IV of the Complaint alleges a breach of express warranty. "Federal courts in Pennsylvania are split" as to whether such a breach of express warranty is a viable cause of action against manufacturers of prescription medical devices. Doughtery, 2012 WL 2940727, at *8. This Court concludes that such a claim is permitted. "While the reasoning of comment k may

prevent certain warranties or promises from being implied by law," there is "no basis for declining to enforce a contractual promise expressly and voluntarily made by a manufacturer of prescription drugs or devices." Id. Accordingly, defendants' Motion on this ground is denied.

Count V of the Complaint also alleges a "Breach of Implied Warranty against All Defendants." The Complaint does not specify whether Count V claims a breach of the implied warranty of merchantability or a breach of the implied warranty of fitness for a particular purpose. Regardless, "[b]oth claims are not cognizable under Pennsylvania law to the extent they are based on a design defect or failure to warn, but are permissible if based on manufacturing defect or any other theory." Tatum, 2012 WL 5182895, at *3.

Count V appears to be based on a claim of design defect. It avers that the Prolene TM soft mesh were "unsafe for their intended use . . . in that they had very dangerous propensities when put to their intended use and implanted into the patient's body and would cause serious injuries to the user." (Compl. at ¶54.) Accordingly, defendants Motion on this ground is granted, and Count V is dismissed without prejudice to plaintiff's right to file an amended complaint consistent with this Order if warranted by the facts.

Finally, Count VII of the Complaint alleges fraudulent misrepresentation. Defendants argue that this claim must be dismissed because it is not based on a theory of negligence. However, "the court in Hahn stated that a seller of prescription drugs must not only warn of risks of which he reasonably should have knowledge, but also warn of risks of which he did, in fact, have knowledge." Tatum, 2012 WL 5182895 at *4. Accordingly, courts have found fraud claims concerning prescription medical devices cognizable if they contain allegations of "overt acts," such as affirmative misrepresentations, "that go beyond a mere failure to warn." James v.

Stryker Corp., 2011 WL 292240, at *3-*4 (M.D. Pa. Jan. 27, 2011); see also Tatum 2012 WL 5182895, at *4. In this case, plaintiff avers that defendants made affirmative misrepresentations concerning the testing of Prolene TM soft mesh, the history of their use, and the risks and benefits of their use. By alleging such affirmative misrepresentations on the part of defendants, plaintiff has stated a claim for fraud and defendants' motion on this ground is denied.

IV. CONCLUSION

For the foregoing reasons, defendant's motion is granted as to Counts II and III and those Counts are dismissed with prejudice. Defendant's motion is granted as to Count V of the Complaint and that Count is dismissed without prejudice to plaintiff's right to file an amended complaint consistent with this Order if warranted by the facts. Defendant's motion is denied in all other respects. An appropriate order follows.